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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/360,685	07/26/1999	ANTONELLO COVACCI	CHIR-0157	4520

27476 7590 11/25/2003

Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/25/2003

42

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/360,685

Applicant(s)

COVACCI ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40 and 41 ~~is/are~~ allowed.
- 6) ☒ Claim(s) 45, 47, 54, 56, 62, 68, 76, 78, 81, 88, 93, 123-125 and 130 ~~is/are~~ rejected.
- 7) ☐ Claim(s) 57, 59, 63, 70, 80, 126-128 and 140 ~~is/are~~ objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence search report.

Continuation of Disposition of Claims: Claims pending in the application are 40,41,45,47,54,56,57,59,62,68,70,78,80,81,88,93,123-128,130 and 140.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 07/30/03 (paper no. 41) in response to the non-final Office Action mailed 05/20/03 (paper no. 40).

Status of Claims

- 2) Claims 45, 47, 54, 56, 57, 59, 62, 63, 70, 76, 78, 80, 81, 88, 93, 123-126 and 130 have been amended via the amendment filed 07/30/03.

Claims 72, 75, 82-87, 89-91, 121, 122 and 139 have been canceled via the amendment filed 07/30/03.

New claim 140 has been added via the amendment filed 07/30/03.

Claims 45, 54, 56, 57, 59, 62, 63, 70, 75, 78, 80 and 81 have been amended via the amendment filed 02/26/03.

Claims 40, 41, 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 76, 78, 80, 81, 88, 93, 123-128, 130 and 140 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

- 5) The rejection of claims 72, 75, 82-87, 121 and 122 made in paragraph 11 of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

- 6) The rejection of claim 139 made in paragraph 16 of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, abstract), is moot in light of Applicants' cancellation of the claim.

- 7) The rejection of claims 75, 82-86 and 89-91 made in paragraph 17 of the Office Action

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mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 102(e) as being anticipated by Cover *et al.* (US 5,403,924), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

8) The rejection of claims 45, 47, 56, 62, 76, 78 and 93 made in paragraph 11(a) of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

9) The rejection of claim 81 made in paragraph 11(c) of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

10) The rejection of claims 123-125 and 130 made in paragraph 11(d) of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

11) The rejection of claims 45, 54, 62, 78, 81 and 126 made in paragraph 11(e) of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

12) The rejection of claims 45, 54, 62 and 78 made in paragraph 11(f) of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn.

13) The rejection of claim 126 made in paragraphs 11(g) and 11(h) of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claims 45, 54, 57, 62, 63, 70 and 78 made in paragraph 11(m) of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

15) The rejection of claims 57, 59, 68, 88, 127 and 128 made in paragraph 11(n) of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

16) The rejection of claims 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 76, 76, 78, 80, 81, 88 and 93 made in paragraph 12 of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to

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the claims.

17) The rejection of claims 93 and 130 made in paragraph 13 of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claims.

18) The rejection of claims 57, 59, 63, 70 and 80 made in paragraph 14 of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 112, first paragraph, as not providing adequate written description, is withdrawn in light of Applicants' amendment to the claims.

19) The rejection of claim 81 made in paragraph 15 of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 102(e) as being anticipated by Keene (US 5,541,291), is withdrawn in light of Applicants' amendment to the claim. A modified rejection to meet the amended claim is made below.

20) The rejection of claims 93, 126, 128 and 130 made in paragraph 17 of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 102(e) as being anticipated by Cover *et al.* (US 5,403,924), is withdrawn in light of Applicants' amendment to the claims.

Rejection(s) Maintained

21) The rejection of claims 45, 47, 54, 56, 62, 68, 76, 78, 81, 88 and 123-125 made in paragraph 17 of the Office Action mailed 05/20/03 (paper no. 40) under 35 U.S.C. § 102(e) as being anticipated by Cover *et al.* (US 5,403,924), is maintained for reasons set forth therein and herebelow.

Applicants acknowledge that Cover's patent taught an amino acid sequence having EFKNGKNKDFSK, EPIYA or NNNNNN. Applicants contend that instant claims, drawn to *Helicobacter pylori* CAI antigen having SEQ ID NO: 9, SEQ ID NO: 10, or six asparagines, have priority over Cover *et al.* ('924), because Applicants' Italian priority application FI/92/A/52, filed 03/02/92, disclosed SEQ ID NO: 9 and 10, and the six asparagine stretch. Applicants allege that these sequences were added to the Cover patent with its April 26, 1993 submission.

Applicants' arguments have been carefully considered, but are non-persuasive. Cover *et al.* get priority to their 859-long polypeptide of SEQ ID NO: 2 since this polypeptide was present in their 1992 priority application. Cover's 859 amino acid-long polypeptide did include the instantly recited SEQ ID NO: 9 at positions 748 to 759 of their polypeptide. Furthermore, contrary to

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Applicants' assertion, Applicants' priority document does not have support for the individually recited fragments, i.e., SEQ ID NO: 9, SEQ ID NO: 10, and six asparagine peptide, because these fragments were not identified in the priority document by a box, as in Figure 4 of the instant specification. Figure 3 of Applicants' priority document lacks identification of these specific fragments within the polypeptide by any specific underlining or boxing. Additionally, the full structure of the recited SEQ ID NO: 9 does not have support in Applicants' priority document. The patent of Cover *et al.* ('924) is properly applied under 35 U.S.C. § 102(e). Therefore, the rejection stands.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments and/or the submission of new claims.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

22) Claim 76 is rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 76, as amended, now depends from claim 47. Claim 76 is confusing, and it does not further limit claim 47, since both claims cover a polypeptide comprising at least fifteen contiguous amino acids of SEQ ID NO: 5.

Rejection(s) under 35 U.S.C § 112, First Paragraph

23) Claims 93 and 130 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 93 and 130 include the new limitation: '748-977 ... the amino acid sequence of' SEQ ID NO: 5" and "2776-3466 .. the nucleotide sequence of' SEQ ID NO: 4 respectively. However, there appears to be no descriptive support in the instant specification for these limitations. Applicants have not pointed to a part of the specification that provides descriptive support for these limitations. Therefore, the limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly

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unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim(s), or invited to point to specific pages and line numbers in the originally filed specification where support for such recitations can be found.

Rejection(s) under 35 U.S.C. § 102

24) Claims 93 and 130 are rejected under 35 U.S.C. § 102(e) as being anticipated by Cover *et al.* (US 5,403,924 - already of record) ('924).

Cover *et al.* ('924) disclosed an isolated polypeptide comprising at least five contiguous amino acids from residues 748 to 977 of the instantly recited amino acid sequence of SEQ ID NO: 5. The prior art polypeptide comprises Glu Phe Lys Asn Gly Lys Asn Lys Asp Phe Ser Lys Val Thr Gln Ala Lys Ser Asp residues which constitutes an at least five contiguous amino acid residue-long fragment of the instantly claimed SEQ ID NO: 5 within the positions 748-977 (see columns 31 and 32 of the '924 patent) and includes the instantly recited SEQ ID NO: 9, i.e., EFKNGKNKDFSK. This prior art polypeptide comprising Glu Phe Lys Asn Gly Lys Asn Lys Asp Phe Ser Lys Val Thr Gln Ala Lys Ser Asp residues is encoded by an at least forty-five contiguous nucleotides of the instantly recited nucleotide sequence of SEQ ID NO: 4, which nucleotide bases fall within positions 2776-3466 of the instantly recited SEQ ID NO: 4. See the attached sequence search report and columns 31 and 32 of the '924 patent.

Claims 93 and 130 are anticipated by Cover *et al.* ('924).

25) Claims 81 and 88 are rejected under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, abstract, already of record).

The recitation 'isolated from the *Helicobacter pylori* .. CAI .. antigen' in claim 81, and the recitation 'recombinant' in claim 88 are viewed as process limitations in a product claim.

Peterson *et al.* taught a purified recombinant polypeptide comprising the amino acid sequence of SEQ ID N: 10, EPIYA. See abstract; and the sequence search report attached to the Office Action mailed 05/20/03. The prior art polypeptide is structurally identical to the instantly claimed polypeptide, irrespective how and from where it is isolated. Peterson's polypeptide is the same as Applicants' polypeptide based upon the fact that every structural characteristic overlapping in

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Paterson's and Applicants' disclosure are the same.

It should be noted that when claims are drawn to a product-by-process, claims are not limited to the manipulations of the recited step(s), but only the structure implied by the steps. MPEP § 2113 states:

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicants have not shown that the alleged difference(s) in the isolation process results in a product that is structurally different from the product of the prior art. In the instant case, Applicants have not shown that the underlying structure of the prior art polypeptide differs from that of the instantly claimed polypeptide.

Claims 81 and 88 are anticipated by Peterson *et al.*

Remarks

26) Claims 45, 47, 54, 56, 62, 68, 76, 78, 81, 88, 93, 123-125 and 130 stand rejected. Claims 40 and 41 are allowable. Claims 57, 59, 63, 70, 80, 126-128 and 140 stand objected to for being dependent from a rejected claim. Claim 127 is grammatically incorrect.

27) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

28) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile

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transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

29) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER

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RESULT 12
:US-08-053-614-1
: Sequence 1, Application US/08053614
: Patent No. 5403924
: GENERAL INFORMATION:
: APPLICANT: COVER, TIMOTHY L.
: APPLICANT: BLASER, MARTIN J.
: APPLICANT: TUMMURU, MURALI K.R.
: TITLE OF INVENTION: THE tagA GENE AND METHODS FOR DETECTING
: TITLE OF INVENTION: PREDISPOSITION TO PEPTIC ULCERATION
: NUMBER OF SEQUENCES: 4
: CORRESPONDENCE ADDRESS:
:
: ADDRESSEE: NEEDLE & ROSENBERG, P.C.
: STREET: 133 Carnegie Way, Suite 400
: CITY: Atlanta
: STATE: Georgia
: COUNTRY: USA
: ZIP: 30303
: COMPUTER READABLE FORM:
: MEDIUM TYPE: Floppy disk
: COMPUTER: IBM PC compatible
: OPERATING SYSTEM: PC-DOS/MS-DOS
: SOFTWARE: PatentIn Release #1.0, Version #1.25
: CURRENT APPLICATION DATA:
: APPLICATION NUMBER: US/08/053,614
: FILING DATE: 19930426
: CLASSIFICATION: 435
: ATTORNEY/AGENT INFORMATION:
: NAME: SPRATT, GWENDOLYN D.
: REGISTRATION NUMBER: 36,016
: REFERENCE/DOCKET NUMBER: 2200.009
: TELECOMMUNICATION INFORMATION:
: TELEPHONE: 404/688-0770
: TELEFAX: 404/688-9880
: INFORMATION FOR SEQ ID NO: 1:
: SEQUENCE CHARACTERISTICS:
: LENGTH: 3648 base pairs
: TYPE: NUCLEIC ACID
: STRANDEDNESS: double
: TOPOLOGY: linear
: MOLECULE TYPE: DNA (genomic)
: ORIGINAL SOURCE:
: ORGANISM: Helicobacter pylori
: FEATURE:
: NAME/KEY: CDS
: LOCATION: 1072..3648
US-08-053-614-1

Query Match 8.4%; Score 58; DB 1; Length 3648;
Best Local Similarity 100.0%; Pred. No. 8e-19;
Matches 58; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 GAATTCAAAAATGGCAAAAATAAGGATTTTCAGCAAGGTAACGCAAGCAAAAAGCGACC 58
Db 3313 GAATTCAAAAATGGCAAAAATAAGGATTTTCAGCAAGGTAACGCAAGCAAAAAGCGACC 3370

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